#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Michelle M. Hanna

Appl. No. To be assigned (Continuation of

Appl. No. 09/984,664; Filed: October 30, 2001)

Filed: March 3, 2004

For: Abortive Promoter Cassettes (as

amended)

Confirmation No. To Be Assigned

Art Unit: To Be Assigned

Examiner: To Be Assigned

Atty. Docket: 2072.0010008/LBB/SJE

#### **Information Disclosure Statement**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement (IDS) is being filed within three months of the date of filing of a national application. No statement or fee is required. 37 C.F.R. § 1.97(b).

Copies of the cited documents were submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/984,664, filed October 30, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Tames B. Bryansk

Lawrence B. Bugaisky Attorney for Applicant Registration No. 35,086

Date: March 3, 2004

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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					ATTY. DOCKET NO.		APPLICATION NO.			
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EXAMINER			JMENT	DATE	NAME	CL ASS	CLID CLASS	SILING DATE		
INITIAL	0.04	3,996		12/1976	NAME Ullman et al.	CLASS	SUB-CLASS	FILING DATE		
	AA1	3,996	5,345	12/19/0	Oliman et al.					
	AB1	4,351	1.760	09/1982	Khanna et al.					
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	AC1	4,582	2,788	04/1986	Erlich					
	AD1	4,683	3 194	07/1987	Saiki <i>et al</i> .					
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	AE1	4,739	9,044	04/1988	Stabinsky					
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!	AF1	4,757	7,141	07/1988	Fung et al.					
	AG1	4 786	6,600	11/1988	Kramer et al.					
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***************************************	AH1	5,130	0,238	07/1992	Malek et al.					
	Al1	5,169	9,766	12/1992	Schuster et al.					
<u>-</u> .	AJ1	5,508,178		04/1996	Rose et al.					
	AK1	5.59	5,891	01/1997	Rose et al.					
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	AP1							No		
			OTHER (In	cluding Auth	or, Title, Date, Pertiner	nt Pages, e	tc.)			
	AR	1	Agrawal, S., a radioactive la	and Tang, JY., beling," <i>Tetrahe</i>	, "Site-specific functionaliza edron Lett. 31:1543-1546, I	ation of oligo Pergamon P	deoxynucleotides f ress (1990)	or non-		
	AS	1	Chamberlin, M.J., "Bacterial DNA-Dependent RNA Polymerases," in <i>The Enzymes</i> , Boyer, P.D. Academic Press, New York, N.Y. pp. 61, 84-86 (1982)							
	АТ	1	Costas, C., e	<i>t al.</i> , "RNA-protoking ATP analo	ein crosslinking to AMP res og," <i>Nucleic Acids R</i> es. 28:	sidues at inte 1849-1858, (	ernal positions in R Oxford University F	NA with a new Press (May 2000)		
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	ATTY, DOCKET NO.	APPLICATION NO.
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	Michelle M. Hanna	
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EXAMINER		DOCUMENT					i
NITIAL		NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,648,211	07/1997	Fraiser et al.			
·	AB2	5,654,142	08/1997	Kievits et al.			
	AC2	5,679,512	10/1997	Laney et al.			
<del></del>	AD2	5,683,879	11/1997	Laney et al.			
	AE2	5,744,308	04/1998	Guillou-Bonnici et al.			
	AF2	5,766,849	06/1998	McDonough et al.			
	AG2	5,824,517	10/1998	Cleuziat et al.			_
	AH2	5,858,801	01/1999	Brizzolara			
	Al2	6,008,334	12/1999	Hanna		-	
	AJ2	6,107,037	08/2000	Sousa et al.			
	AK2	6,107,039	08/2000	Hanna			
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	AR	2 RNA-D	S.S., and von Hi NA Bubble Duple e (1992)	ppel, P.H., "Functional Transo xes," <i>Science 258</i> :1320-1324	cription Elongation, American Asso	on Complexes fro ociation for the A	om Synthetic dvancement of
	AS	2 Dunn, Cocation	J.J., and Studier, ns of T7 Genetic	F.W., "Complete Nucleotide S Elements," <i>J. Mol. Biol.</i> 166:4	Sequence of Bac 77-535, Acaden	eteriophage T7 D nic Press, Inc. (1	NA and the 983)
	АТ	2 Gait, M Oxford	l.J., et al., "Oligori University Press,	ibonucleotide synthesis," in O Oxford, Great Britain, pp. 25	ligonucleotides a 31 (1992)	and Analogues, E	Eckstein, F., ed
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XAMINER		DOCUMENT					
VITIAL		NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3	5,399,491	03/21/95	Kacian <i>et al</i> .			03/19/92
	AB3	5,888,819	03/30/99	Goelet et al.			03/05/91
	AC3	5,554,516	09/10/96	Kacian et al.			12/02/93
	AD3	5,571,669	11/05/1996	Lu et al.			01/14/1993
	AE3	6,251,594 B1	06/26/2001	Gonzalgo et al.			06/09/1998
	AF3	2003/0099950 A1	05/29/2003	Hanna, M.M.			10/30/2001
	AG3						
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XAMINER VITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
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	AL3	<del> </del>					Ye
	AM3						Ye
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	AR	Gait, M.J., practical ap	"An Introduction pproach, Gait, M	n to Modern Methods of D M.J., ed., Oxford Universit	NA Synthesis," in 6 y Press, Oxford, Gr	Oligonucleotide s reat Britain, pp.1	synthesis: a -22 (1984)
	AS	Geider, K., form conve	et al., "An RNA rsion," <i>Proc. N</i>	A transcribed from DNA at atl. Acad. Sci. USA 75:64	the origin of phage 5-649, National Aca	efd single strand ademy Press (19	to replicative 78)
	AT	Guatelli, J. modeled at (1990)	C., et al., "Isoth fter retroviral re	ermal, <i>in vitro</i> amplificatio plication," <i>Proc. Natl. Aca</i>	n of nucleic acids t d. Sci. USA 87:187	oy a multienzyme 4-1878, Nationa	e reaction I Academy Pre
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	AO4							Yes No
	AP4							Yes No
	<b></b>		OTHER	(Including A	uthor, Title, Date, P	Pertinent Pages, etc	.)	
	AR	4	Gupta, K.t	C., <i>et al</i> ., "A ge oligonucleotid	eneral method for the sy des," <i>Nucleic Acids Res</i>	ynthesis of 3⊡-sulfhydr s. 19:3019-3025, Oxfor	yl and phosphat d University Pres	e group ss (1991)
	AS	4	Gurevich, Anal. Biod	V.V., et al., "P hem. 195:207	reparative <i>in Vitro</i> mRN- -213, Academic Press,	NA Synthesis Using SF Inc. (1991)	6 and T7 RNA F	olymerases,"
	AT	4	Hanna, M Enzymol.	.M., "Photoaffi 180:383-409,	nity Cross-Linking Meth Academic Press, Inc. (	nods for Studying RNA 1989)	-Protein Interacti	ons," <i>Methods</i>
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	AR	5	elongat	M.M., et al., "Pi ion complexes u exford University	robing the environment of utilizing a new fluorescent y Press (1999)	nascent RNA in <i>Esch</i> ribonucleotide analog	erichia coli trans ," Nucleic Acids	cription Res. 27:1369-
	AS	<u>5</u>	in photo	M.M., et al., "S paffinity labeling sity Press (1993	ynthesis and characterizat <i>E.coli</i> and T7 RNA polyma )	ion of a new photocro erases," <i>Nucleic Acid</i>	sslinking CTP a s Res. 21:2073-:	nalog and its us 2079, Oxford
	АТ	<u>5</u>	He, B.,	et al., "Preparations," <i>Nucleic A</i>	tion of probe-modified RNA cids Res. 23:1231-1238, (	A with 5-mercapto-UT Oxford University Pres	P for analysis of ss (1995)	f protein-RNA
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	ATTY, DOCKET NO.	APPLICATION NO.
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	AL6								Yes No	
	AM6								Yes No	
	AN6								Yes No	
	A06								Yes No	
	AP6								Yes No	
			OTHER (	Including Au	thor, Title, Date, P	ertinent P	ages, etc.	)		
	Kwoh, D.Y., et al., "Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format," <i>Proc. Natl. Acad. Sc. USA 86</i> :1173-1177, National Academy Press (1989)								d human :. Natl. Acad. Sci.	
	AS	<u>6</u>	Polymeras	Lewis, M.K., and Burgess, R.R., "Transcription of Simian Virus 40 DNA by Wheat Germ RNA Polymerase II," <i>J. Biol. Chem. 255</i> :4928-4936, American Society for Biochemistry and Molecular Biology (1980)						
	AT	<u>6</u>	Martin, C.1 27:3966-39	Γ., <i>et al.</i> , "Proce 974, American (	essivity in Early Stages Chemical Society (198	s of Transcr 38)	iption by T7	RNA Polymera	se," <i>Biochemistry</i>	
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	AR	7	Meyer, K Deoxyuri	I and Hanna	, M.M., "Synthesis and Cha amidite for Site-Specific Mo	aracterization of a N	ew 5-Thiol-Prote	ected eem. 7:401-412,
	AS	Z	Milligan, J.F., and Uhlenbeck, O.C., "Synthesis of Small RNAs Using T7 RNA Polymerase," <i>Methods Enzymol.</i> 180:51-62, Academic Press, Inc. (1989)					
	AT	7	Montema motors,"	agno, C., and E Nanotechnolog	achand, G., "Constructing 10:225-231, IOP Publish	nanomechanical de ing, Ltd. (1999)	vices powered b	y biomolecular
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	AM8							Yes No	
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	AN8							Yes No	
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	AR	8	Mullis K	et al "Specif	ic Enzymatic Amplification b. Quant. Biol. 51:263-273,	of DNA In Vitro: The	Polymerase Ch	nain Reaction," 36)	
	AS	8	Mullis, K. Erlich, H.	Mullis, K.B., et al., "The Polymerase Chain Reaction: Why It Works," in Polymerase Chain Reaction Erlich, H.A., et al., eds., Cold Spring Harbor Laboratory Press, Woodbury, N.Y., pp. 237-243 (1989)					
	AT	8	Nelson, P.S., et al., "Bifunctional oligonucleotide probes synthesized using a novel CPG support are able to detect single base pair mutations," Nucleic Acids Res. 17:7187-7194, Oxford University Press (1989)						
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	AR	9	Pringsheim, P., "Fluorescence of organic compounds,"in Fluorescence and phosphorescence, Pringsham, P., ed., Interscience Publishers, Inc. New York, N.Y., pp. 392-397, 420-423 (1949)						
	AS	9	Saiki, R.K., et al., "Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase," Science 239:487-491, American Association for the Advancement of Science (1988)						
	AT	9	Oligonu	N.D., and Striep cleotides and A 0, 200-201 (199	oeke, S., "Oligonucleotides v Analogues: A Practical Appro 92)	with reporter groups oach, Eckstein, F., e	attached to the d., Oxford Unive	5⊡-terminus," in ersity Press pp.	
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	Smithies, O., et al., "Detection of Targeted Gene Modifications by Polymerase Option of Polymerase Chain Reaction, Erlich, H.A., et al., eds., Cold Spring Harbor Labor N.Y., pp. 199-203(1989)					merase Chain R or Laboratory P	eaction," in ress, Woodbury,		
	AS	<u>10</u>	Sproat, B.S., et al., "The synthesis of protected 5□-mercapto-2□,5□-dideoxyribonucle phosphoramidites; uses of 5□-mercapto-oligodeoxyribonucleotides," <i>Nucleic Acids Re</i> Oxford University Press (1987)					oside-3⊡-O- s. <i>15</i> :4837-4848,	
	АТ	<u>10</u>	Walker, G system," F	.T., et al., "Iso Proc. Natl. Aca	thermal <i>in vitro</i> an d. Sci. USA 89:39	plification of DI 2-396, Nationa	NA by a restri I Academy Pr	ction enzyme/DI ess (1992)	NA polymerase
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	ATTY, DOCKET NO.	APPLICATION NO.
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	AS	11 Daube Comple	Daube et al., "Functional Transcription Elongation Complexes from Synthetic RNA-DNA Bubble Complexes," Science, 1992, vol. 258, pages 1320-1324						
	AT	11 Mancir Retino	ni <i>et al</i> , "Constit blastoma Gene (	utively Methylated CpG Din RB1), American Journal of	ucleotides as Mutati Human Genetics, 19	on Hot Spots in 997, vol. 61, pag	the es 80-87		
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ATTY, DOCKET NO.	APPLICATION NO.
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	AR	<u>12</u>	Internationa Internationa	al Search Rep al Searching	oort for International Ap Authority/USA, Washin	oplication No. F gton, D.C.	PCT/US02	2/34419, mailed	July 24, 2003,
	AS	<u>12</u>	Antequerra, Acad. Sci. I	, F., and Bird <i>JSA 90</i> :1199	, A., "Number of CpG i 5-11999, National Aca	slands and ger demy of Sciend	nes in hur ces (1993	man and mouse 3)	," Proc. Natl.
	АТ	<u>12</u>	Callahan, R Academy o	k., <i>et al</i> ., "Fre f Sciences (1	quent Mutations in Bre 993)	ast Cancer," A	nn. N.Y.	Acad. Sci. 698:2	21-30, New York
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	AS	<u>13</u>	Ovarian Tu	, <i>et al.</i> , "Promo mors," <i>J. Natl</i> . Nexis Academi	Cancer Inst. 92:564-5	and BRCA1 Inactivation (1996), Oxford University (1996)	on in Sporadic B Press (April 2000	reast and 0). (Retrieved
	АТ	<u>13</u>	Frommer, I residues in Sciences (*	individual DN	enomic sequencing pro A strands," <i>Proc. Natl.</i>	otocol that yields a pos Acad. Sci. USA 89:18:	itive display of 5 27-1831, Nation	-methylcytosine al Academy of
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	AR	14 G	iusti, W ligonuc	.G., and Adrian leotides," <i>PCR</i>	o, T., "Synthesis and Cha Methods Appl. 2:223-227	aracterization of 5'-Fli 7, Cold Spring Harbor	uorescent-dye-la Laboratory Pre	abeled ss (1993)
	AS	<u>14</u> G	Supta, K ligonucl	.C., et al., "A ge eotides," <i>Nucl</i> e	eneral method for the syn ic Acids Res. 19:3019-30	thesis of 3'-sulfhydryl 25, Oxford University	and phosphate Press (1991)	group containing
	АТ	14 A	berrant	<b>DNA Methylatic</b>	activation of the <i>CDKN2/p</i> on in All Common Humar Research (1995)	o16/MTS1 Gene Is Fr n Cancers," Cancer R	equently Associ	ated with 30, American
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	AS	<u>15</u>	Horii, A., et Primary Ca	al., "Frequen ncers," Canc	t Replication Errors at er Res. 54:3373-3375,	Microsatellite Loci in American Association	Tumors of Patient of for Cancer Rese	s with Multiple earch (1994)
	АТ	<u>15</u>	Issa, JP.J human cold	., et al., "Metr on," <i>Nat. Gen</i> o	nylation of the oestroge et. 7:536-540, Nature F	en receptor CpG islan Publishing Co. (1994)	d links ageing and	d neoplasia in
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	AR	<u>16</u>	Jin, D.J., " Abortive Ir	An <i>Escherichi</i> nitiation Produ	a coli RNA Polymerase D cts," <i>J. Mol. Biol.</i> 236:72-	Defective in Transcript 80, Academic Press L	ion due to its O imited (1994)	verproduction of
	AS	<u>16</u>	Langer, P. probes," F	R., et al., "En: Proc. Natl. Aca	zymatic synthesis of biotind. Sci. USA 78:6633-663	n-labeled polynucleoti 7, National Academy	des: Novel nucl of Sciences (19	eic acid affinity 81)
	AT	<u>16</u>	Loeb, L.A. 51:3075-3	., "Mutator Pho 079, America	enotype May Be Required n Association for Cancer	d for Multistage Carcir Research (1991)	nogenesis," <i>Cai</i>	acer Res.
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	AR	<u>17</u>	Meinkoth, J. Biochem. 13	, and Wahl, G., ' 8:267-284, Aca	'Hybridization of Nuclei demic Press, Inc. (1984	c Acids Imm	obilized	on Solid Suppo	orts," <i>Anal</i> .
	AS	<u>17</u>	Nowell, P.C. Association	, "The Clonal Ev for the Advance	olution of Tumor Cell F ment of Science (1976)	Populations,"	Science	. <i>194</i> :23-28, Ar	nerican
	АТ	<u>17</u>	Palmisano, \ Sputum," Ca	W.A., et al., "Pre ancer Res. 60:59	edicting Lung Cancer by 954-5958, American As	/ Detecting A sociation for	Aberrant Cancer	Promoter Meth Research (Nov	ylation in /ember 2000)
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FIRST NAMED INVENTOR Michelle M. Hanna

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	AS	<u>18</u>	Rice, J.C., 6 decreased I (1998)	et al., "Aberrar BRCA1 mRNA	nt methylation of the E	BRCA1 CpG is ancer cells," C	sland prom Oncogene	noter is associat 17:1807-1812, \$	ed with Stockton Press
	AT	18	Robertson, Publishing	K.D., "DNA m Group (May 20	ethylation, methyltran 001)	sferases, and	cancer,"	Oncogene 20:3	139-3155, Nature
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	AS	<u>19</u>							
	АТ	<u>19</u>	Toyota, M., and Issa, JP.J., "The role of DNA hypermethylation in human neoplasia," <i>Electrophoresis</i> 21:329-333, Wiley-VCH Verlag GmbH (January 2000)						
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AR 20 Vogelstein, B., and Kinzler, K.W., "The multistep nature of cancer," <i>Trend</i> Science Publishers Ltd. (1993)							nds Genet. 9:13	38-141, Elsevier	
	AS	<u>20</u>	Wang, J\ promoter o	∕., et al., "Mon of Escherichia	ovalent cations differ in t coli, " Gene 196:95-98, E	neir effects on transcr Elsevier Science B.V.	iption initiation f (1997)	from a σ-70	
	АТ	<u>20</u>	Wu, D.Y., and Wallace, R.B., "The Ligation Amplification Reaction (LAR) - Amplification of Specific DNA Sequences Using Sequential Rounds of Template-Dependent Ligation," <i>Genomics</i> 4:560-569, Academic Press, Inc. (1989)						
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